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| | | | | Application Number | 10/562,377 |
| | | | | Filing Date | August 25, 2006 |
| | | | | First Named Inventor | Cathy Lofton-Day |
| | | | | Art Unit | 1645 |
| | | | | Examiner Name | Not yet assigned |
| Sheet | 1 | of | 3 | Attorney Docket Number | 47675-163 |

| U.S. PATENT DOCUMENTS | | | | | | | |
|---------------------------------|--------------------------|---|--------------------------------|--|---|--|----------------|
| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | | |
| | | Number-Kind Code ¹ (if known) | | | | | |
| | | US- 5565552 | | | | | |
| | | US- 5567810 | | | | | |
| | | US- 5574142 | | | | | |
| | | US- 5585481 | | | | | |
| | | US- 5587371 | | | | | |
| | | US- 5597696 | | | | | |
| | | US- 5786146 | | | | | |
| | | US- 5958773 | | | | | |
| | | US- 6251594 | | | | | |
| | | US- 6265171 | | | | | |
| | | US-6331393 | | | | | |
| | | US- 2003/0013091 | | | | | |
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| FOREIGN PATENT DOCUMENTS | | | | | | | |
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| | | Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | | | | | |
| | | WO 95/00669 | | | | | |
| | | WO 95/15373 | | | | | |
| | | WO 97/46705 | | | | | |
| | | WO 99/28498 | | | | | |
| | | WO 00/26401 | | | | | |
| | | WO 02/24056 | 03-28-2002 | Case Western Reserve University | | | |
| | | WO 03/014388 | 02-20-2003 | Epigenomics AG | | | |
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| NON PATENT LITERATURE DOCUMENTS | | | | | | | |
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| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|-----------------------|--------------------------|---|----------------|
| | | BOWTELL, "Options available – from start to finish – for obtaining expression data by microarray," Nature Genetics Supplement, January 1999, pp. 25-32, Volume 21 | |
| | | DATABASE EMBL [Online] November 11, 1999, "Homo sapiens BAC clone RP11-538J11 from 2, complete sequence" | |
| | | DATABASE EMBL [Online] "July 16, 2002, "Home sapiens cDNA FLJ40417 fis, clone TESTI2038388, highly similar to Home sapiens gamma cysteine string proteins mRNA" | |
| | | EADS et al., "CpG Island Hypermethylation in Human Colorectal Tumors Is Not Associated with DNA Methyltransferase Overexpression," Cancer Research, May 15, 1999, pp. 2302-2306, Volume 59 | |
| | | FEIL et al., "Methylation analysis on individual chromosomes: improved protocol for bisulphite genomic sequencing," Nucleic Acids Research, 1994, pp. 695-696, Volume 22, No. 4 | |
| | | FROMMER et al., "A genomic sequencing protocol that yields a positive display of 5-methylcytosine residues in individual DNA strands," PNAS, March 1992, pp. 1827-1831, Volume 89 | |
| | | GONZALGO et al., "Identification and Characterization of Differentially Methylated Regions of Genomic DNA by Methylation-sensitive Arbitrarily Primed PCR," Cancer Research, February 15, 1997, pp. 594-599, Volume 57 | |
| | | GONZALGO et al., "Rapid quantitation of methylation differences at specific sites using methylation-sensitive single nucleotide primer extension (Ms-SNuPE), Nucleic Acids Research, 1997, pp. 2529-2531, Volume 25, No. 12 | |
| | | GRIGG et al., "Sequencing 5-Methylcytosine Residues in Genomic DNA," BioEssays, June 1994, pp. 431-436, Volume 16, No. 6 | |
| | | GUT et al, "DNA and Matrix Assisted Laser Desorption Ionization Mass Spectrometry," Molecular Biology: Current Innovations and Future Trends, 1995, pp. 147-157, Horizon Scientific Press, Wymondham, United Kingdom | |
| | | GUT et al., "A procedure for selection DNA alkylation and detection by mass spectrometry," Nucleic Acids Research, 1995, pp. 1367-1373, Volume 23, No. 8 | |
| | | HEID et al., "Real Time Quantitative PCR," Genome Research, 1996, pp. 986-994, Volume 6 | |
| | | HERMAN et al., "Methylation-specific PCR: A novel PCR assay for methylation status of CpG islands," September 1996, pp. 9821-9826, Volume 93 | |
| | | KARAS et al., "Laser Desorption Ionization of Proteins with Molecular Masses Exceeding 10 000 Daltons," Analytical Chemistry, October 15, 1988, pp. 2299-2301, Volume 60, No. 20 | |
| | | LIPSHUTZ et al., "High density synthetic oligonucleotide arrays," Nature Genetics Supplement, January 1999, pp. 20-24, Volume 21 | |
| | | MARTIN et al., "Genomic sequencing indicates a correlation between DNA hypomethylation in the 5' region on the pS2 gene and its expression in human breast cancer cell lines," Gene, 1995, pp. 261-264, Volume 157 | |
| | | OLEK et al., "A modified and improved method for bisulphite based cytosine methylation analysis," Nucleic Acids Research, 1996, pp. 5064-5066, Volume 24, No. 24 | |
| | | OLEK et al., "The pre-implantation ontogeny of the H19 methylation imprint," Nature Genetics, November 1997, pp. 275-276, Volume 17 | |
| | | REIN et al., "SURVEY and SUMMARY Identifying 5-methylcytosine and related modifications in DNA genomes," Nucleic Acids Research, 1998, pp. 2255-2264, Volume 26, No. 10 | |

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